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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/286,166 04/05/99 FOWLKES

D CPI-012CP4BC

000959  
LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON MA 02109

HM12/0217

EXAMINER

BRANNOCK, M

ART UNIT

PAPER NUMBER

1646

6

DATE MAILED: 02/17/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/286,166**

Applicant(s)

**Fowikes, DM et al.**

Examiner  
**Michael Brannock, Ph.D.**

Group Art Unit  
**1646**



☒ Responsive to communication(s) filed on Apr 5, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1646

## DETAILED ACTION

### *Status of Application: Amendments and Claims*

1. Applicant's preliminary amendments put forth in Paper 4, 4/5/99, have been entered in full.
2. Claims 2-42 have been canceled per Applicant's amendment in Paper 4, 4/5/99.
3. Claim 1 is pending in the instant application.

### *Specification*

4. The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. Correction is required. See M.P.E.P. 2422.04. Also, the instant application fails to comply with sequence rules because there is no paper copy of the Sequence listing, i.e., a paper copy cannot be transferred. The instant application must contain a paper copy of the sequence listing as supplied by Applicant through amendment.

### *Double Patenting*

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 1 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,789,184. Although the

Art Unit: 1646

conflicting claims are not identical, they are not patentably distinct from each other for the following reasons: claim 1 of US 5,789,184 requires a yeast cell expressing a heterologous surrogate of a yeast pheromone system protein and a second heterologous peptide, wherein the second heterologous peptide modulates the interaction of the said surrogate protein with the pheromone system, and said modulation is a selectable or screen able event. Thus all of the limitations required by claim 1 of the instant application are met by claim 1 of US 5,789,184.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites (a) a heterologous surrogate of a yeast cell pheromone system protein and (b) a heterologous peptide. It is unclear if the protein of (b) is heterologous to the polypeptide of (a) or to the yeast cell. Also it is unclear if the protein of (a) and the peptide of (b) are the same polypeptide or that (a) and (b) are distinct polypeptides. If the Applicant intends the meaning of the claim to be the latter, then one way in to obviate this rejection is to reword the claim such that it recites "..., and (b) a second heterologous peptide, ...".

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1646

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by King, K., *et al.* (*Science* 250(121-123)1990)). King, K., *et al.* (*supra*) teach a yeast cell having a pheromone system, which cell expresses (a) a heterologous surrogate of a yeast pheromone system protein (e.g. h $\beta$ -Ar is a surrogate of the yeast pheromone receptor - see the Abstract) performing a function naturally performed by the corresponding yeast pheromone system protein (e.g., heterologous h $\beta$ -Ar induces activation of the yeast pheromone response pathway - see the Abstract), and (b) a heterologous peptide (e.g. mammalian G $_s$  $\alpha$  subunit - see the Abstract), whereby if said peptide modulates the interaction of said surrogate with said pheromone system (e.g. G $_s$  $\alpha$  couples to h $\beta$ -Ar and further transduces the activation of the pheromone response - see the Abstract), said modulation is a selectable marker (e.g. characteristic morphological change of yeast - see page 122, col. 2).

***Additional Relevant References***

11. Pausch, M.H., TIBTECH 15(487-494)1997 is considered relevant to the instant application because the Author, citing published work by Applicant and colleagues, states that "yeast expression libraries designed for the secretion of random small peptides have been designed. When the secreted peptide derived from the library plasmid is expressed in yeast along with a GPCR, an autocrine loop is established, resulting in the growth of cells that express an active peptide. Using this scheme, novel agonists and antagonists of the yeast  $\alpha$ -mating-type pheromone receptors were identified, suggesting it may also be useful for heterologous GPCRs.

Art Unit: 1646

***Conclusions***

12. Claim 1 is not allowed.


13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

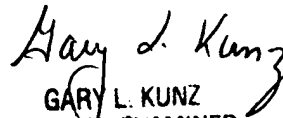
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D., can be reached at (703) 308 - 4623.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

  
February 14, 2000

  
GARY L. KUNZ  
PRIMARY EXAMINER  
GROUP 1200